Please delete claim 7 without prejudice, the subject matter thereof appearing in new claim 13.

Please delete claim 8 and insert therefor new claim 14 as follows:

14 (New). An isolated polypeptide in accordance with claim 13, wherein the protein of (a) has the sequence of SEQ ID NO: 4.

Please amend claim 9 as follows:

9 (Amended). A molecule which comprises the antigen-binding portion of an antibody specific for a protein, variant or fragment in accordance with claim 13.

REMARKS

Claims 9, 13 and 14 presently appear in this case. No claims have been allowed. All of the claims have been subject to a restriction requirement. Reconsideration and withdrawal of the restriction requirement, examination and allowance of all the claims now present in the case are hereby respectfully urged.

The examiner has required restriction among the following groups of allegedly independent and distinct inventions:

Group I, including claims 1-5 drawn to a polynucleotide;

Group II, including claims 6-8 drawn to a polypeptide;

Group III, including claim 9 drawn to antibody;

Group IV, including claim 10 drawn to a method of treating the effect of stroke, hypoxia and/or ischemia;

Group V, including claim 11 drawn to a method of diagnosis; and

Group VI, including claim 12 drawn to a method of screening.

This restriction requirement is respectfully traversed to the extent discussed here and below.

In order to be responsive, applicant hereby elects Group II, drawn to the polypeptides. All of the claims which the examiner designated as appearing in Groups I, IV, V and VI have now been deleted. However, the antibody claim of Group III has not been deleted and the restriction requirement is respectfully traversed insofar as Groups II and III are concerned.

The restriction requirement is respectfully traversed insofar as the antibody of claim 9 is considered to be an independent and distinct invention from the polypeptide of claim 13. Claim 9 reads:

> 9. A molecule which comprises the antigen-binding portion of an antibody specific for a protein, variant or fragment in accordance with claim 13.

Applicants hereby concede that, if the polypeptide of claim 13 were available to the prior art (which includes knowledge of its biological activity as set forth in the claim), it would be *prima facie* obvious, within the meaning of 35 U.S.C. §103, for one of ordinary skill in the art to make an antibody which is specific to such protein. Techniques of raising antibodies, including monoclonal antibodies, are well known and the Patent and Trademark Office routinely rejects claims to monoclonal antibodies as being obvious if the protein against which it is specific is known to the prior art.

It should clearly be understood that the present admission is a one-way admission only. Applicants do not concede that if an antibody is known which happens to bind to a polypeptide of claim 13, this would necessarily make the polypeptide of claim 13 obvious or unpatentable. Furthermore, applicants do not concede that <u>all</u> antibodies specific for a polypeptide of claim 13 are necessarily obvious. Specific monoclonal antibodies may exist having unexpected properties which would not be obvious from prior art knowledge of the protein to which it is specific. However, in the present case, claim 9 is a broad claim to any antibody specific to a

polypeptide of claim 13 and the present concession is simply that there are antibodies within the scope of claim 9 which would not be patentable and would be *prima facie* obvious in the sense of 35 U.S.C. §103 if the protein of claim 13, including its biological properties, were known to the prior art. Knowing the biological activity of such protein, one of ordinary skill in the art would have been motivated to make an antibody for the purpose of immunoaffinity purification or for the purpose of blocking its activity. The techniques for doing so are well known.

In light of the present admission and the provisional election of the protein claims of Group II, a restriction requirement cannot be maintained. If the elected protein claims proceed to issue, any patent issuing on the antibody would have to be subject to an obviousness-type double patenting rejection in view of the above admission. See MPEP §804.II.B.1. relating to double-patenting rejections, which states:

> In determining whether a non-statutory basis exists for a double-patenting rejection, the first question to be asked is - does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent? If the answer is yes, then "obvious-type" non-statutory double-patenting rejection may be appropriate.

However, such a double patenting rejection cannot be made in light of 35 U.S.C. §121. Reference is made to Section 803.01 of the MPEP, where it states:

> Notwithstanding the fact that this section of the statute [35 U.S.C. 121] apparently protects the applicants against the dangers that previously might have resulted from compliance with an improper requirement for restriction, IT STILL REMAINS IMPORTANT FROM THE STANDPOINT OF THE PUBLIC INTEREST THAT NO REQUIREMENTS BE MADE WHICH MIGHT RESULT IN THE ISSUANCE OF TWO PATENTS FOR THE SAME INVENTION. [Emphasis original]

See also 37 C.F.R. §1.601(n) defining the concept of patentably distinct inventions from the interference perspective. This rule states:

> Invention "A" is the **same patentable invention** as an invention "B" when invention "A" is the same as (35 USC 102) or is obvious (35 USC 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".

Here, assuming the protein of claim 13 (invention "B") is prior art to the antibody of claim 9 (invention "A"), the antibody is *prima facie* obvious in light of applicants' admission. Thus, both claims are drawn to the same patentable invention. If they are drawn to the same patentable invention for interference purposes, they should be considered the same patentable invention for all purposes, despite any distinction in the material *per se*. As indicated above, no restriction

requirement can be made which would result in the issuance of two patents for the same invention.

MPEP §803 refers to the case of *In re Lee*, 199 USPQ 108 (Comm'r for Pat 1978) as holding that restriction should not be required if there is an express admission that the claimed inventions are obvious over each other within the meaning of 35 U.S.C. §103. However, such a two-way admission is not necessary as even the one-way admission presently being made is sufficient to result in two patents directed to the same invention. If an antibody claim in one patent would be obvious from a protein claim in another patent, then the two claims are not patentably distinct and the imprimatur of MPEP §803.01 quoted hereinabove must be invoked.

It should be noted that this identical issue has already been made the subject of a petition to the Commissioner by the undersigned with respect to another case and Deputy Director, Mary C. Lee, in a decision published as *In re Gold*, 42 USPQ2d 1095 (Comm'r Pats 1996) confirmed that, in such a circumstance, restriction requirement is not applicable. A copy of that decision was attached hereto. Note particularly where it states at 1096:

> At this point it is noted that the fact that there is an admission that the antibody is obvious in view of the peptide but not an admission that the peptide is obvious over the antibody would not change this decision

> because the Office policy that "no restriction requirements be made which might result in the issuance of two patents for the same invention" would still control.

Reconsideration and withdrawal of this restriction requirement insofar as Groups II and III are concerned are therefore respectfully urged.

The examiner states that each group detailed above reads on patentably distinct sequences and a further restriction is applied to each group. The examiner states that for an elected group applicants must further elect a single amino acid and nucleotide sequence. Examiner states that for Group II, drawn to polypeptides, applicants are required to elect either a single polynucleotide SEQ ID NO: that encodes a polypeptide or a single SEQ ID NO: of a polypeptide itself.

Applicant hereby elects the polypeptide of SEQ ID NO:4 and the corresponding polynucleotide of SEQ ID NO:3, as well as the naturally occurring variants thereof as claimed. Everything within the scope of the new claim 13 is directed to structurally similar sequences. If a species within this genus needs to be elected for examination purposes, applicant hereby elects the species of SEQ ID NO:4. All of the non-elected patentably distinct sequences have now been deleted

without prejudice toward the continuation of the prosecution thereof in divisional applications.

As all of the claims to the non-elected Groups other than Groups II and III have been deleted and as Group III must be examined with Group II for the reasons discussed above, all of claims 9 and 13-14 presently appearing in this case should be examined in the present application. Withdrawal of the restriction requirement to the extent requested herein and examination and allowance of all the claims now present in the case are therefore earnestly solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with markings to show changes made".

Respectfully submitted,

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Version with Markings to Show Changes Made

In the claims:

9 (Amended). A molecule which comprises the antigen-binding portion of an antibody specific for a protein, variant or fragment in accordance with claim ~~6~~13.

Claims 1-5, 7, 8 and 10-12 have been deleted.

Claims 13 and 14 have been added.

counts are predicated on exactly the same conduct as that underlying the copyright counts — *viz.*, copying unique designs." 869 F.Supp. at 1361.

The tortious interference claim, like the UDTPA claims, is preempted because it is in essence a claim of copyright infringement. The fact that the Illinois claims contain an element of deception or misrepresentation does not effect this court's preemption analysis. All of the state-law claims are preempted by the broad reach of 17 U.S.C. §301.

IT IS THEREFORE ORDERED THAT the defendants' motions to dismiss counts III, IV and V (docket # 68 & 72 & 77) are granted.

U.S. Patent and Trademark Office
Commissioner of Patents and Trademarks

In re Gold

PLM Paper No. 18

Decided December 31, 1996
(Unpublished)

PATENTS

1. Practice and procedure in Patent and Trademark Office — Prosecution — Rules and rules practice (§110.0905)

Patentability/Validity — Anticipation — Double patenting (§115.0708)

Patent examiner is directed to withdraw requirement for restriction between claims in protein group and claims in antibody group in patent application, since Manual of Patent Examining Procedure's Section 803 states that restriction should not be required if there is express admission that claimed inventions are obvious over each other within meaning of 35 USC 103, since "patentable distinctness" issue between peptide and antibody groups in application is close, and since admission in present case, although it does not specifically mention 35 USC 103, states that antibody is obvious over peptide; absence of corresponding admission that peptide is obvious over antibody does not warrant contrary decision, in view of Patent and Trademark Office policy that "no restriction requirements be made which might result in the issuance of two patents for the same invention."

Patent application of Leslie I Gold. et al. On applicants' petition requesting that restriction requirement be withdrawn. Petition granted.

[Editor's Note: The U.S. Patent and Trademark Office has not designated this decision as prepared for publication. It is not binding precedent of the Commissioner of Patents and Trademarks.

Roger L. Browdy, of Browdy & Neimark, Washington, D.C., for petitioner.

Lee, deputy director, patent examining group 1800.

This is a decision on the petition under 37 CFR 1.181 and 37 CFR 1.144, filed November 4, 1996, to withdraw the restriction requirement with respect to Groups I/II and VI. Note, petitions from restriction requirements are properly considered under 37 CFR 1.144. Therefore, the petition is being treated as a petition under 37 CFR 1.144.

On April 7, 1995, an Office action was mailed that required restriction between claims 1-9 and 13 (Group I), claims 10-12 (Group II), claims 14-15 (Group III), claim 16 (Group IV), claim 17 (Group V), claim 18 (Group VI), and claims 19 and 20 (Group VII). With an election of Group II, applicant was further required to elect one of two patentably distinct species of the invention. In response to the Office action, applicants timely filed a response on August 7, 1995 in which applicants canceled claims 14-17 drawn to Groups III, IV and V, elected Group I, claims 1-9 and 13, and traversed the restriction requirement insofar as the claims of Groups II, VI and VII were deemed to be independent and distinct from the elected invention. On November 28, 1995, an Office action was mailed which withdrew the requirement for restriction between Groups I/II and Groups VI and VII. In applicants' response filed May 28, 1996, a request for reconsideration of the requirement for restriction with respect to Groups VI and VII was made. On September 4, 1996, a final Office action was mailed which reaffirmed the requirement for restriction. The present petition was filed on November 4, 1996 requesting that the restriction requirement between Groups I and VI be withdrawn at least to the extent of considering claim 5 to be a linking claim so that claim 18 will be considered at the time that claim 5 is allowable.

Petitioner asserts that applicants have conceded that if the protein of claim 5 (from Group I/II) is anticipated or obvious then the antibody of claim 18 (Group VI) would

also be obvious as it would be obvious to make an antibody to any known peptide. Thus, petitioner contents that if a patent issues containing a claim drawn to the protein of claim 5, and a divisional application is filed resulting in the issuance of a claim of the scope of claim 18, two patents will have issued drawn to inventions which are not patentably distinct. Absent 35 U.S.C. 121, a double-patenting rejection would have to be made on the antibody claim because it is admittedly obvious from the protein. Thus, petitioner concludes that the restriction requirement between Groups I/II and VI should be withdrawn.

[1] As argued by petitioner, MPEP § 803 is appropriate here where it states:

> If there is an express admission that the claimed inventions are obvious over each other within the meaning of 35 U.S.C. 103, restriction should not be required, *In re Lee*, 199 USPQ 108 (Deputy Asst. Comm'r. For Pats. 1978).

The decision in *In re Lee* was based not only on the presence of an admission that the claimed inventions are obvious over each other within the meaning of 35 U.S.C. 103 but also on the fact that the issue of "patentable distinctness" between the two groups was close and the Office policy:

> [T]hat it is important from the standpoint of public interest that no restriction requirements be made which might result in the issuance of two patents for the same invention. The nullification of double patenting as a ground of rejection provided for in the third sentence of 35 U.S.C. 121 imposes a heavy burden on the Office to guard against erroneous requirements for restriction where the claims define essentially the same invention and which if acquiesced in, might result in more than one patent for essentially the same invention with attendant prolongation of patent monopoly.

Here, the Office policy is the same as when *In re Lee* was decided and like in *In re Lee*, the "patentable distinctness" issue between the peptide of Group I/II and the antibody of Group VI is close. Lastly, while the admission in this case does not explicitly state that the antibody is obvious over the peptide "within the meaning of 35 U.S.C. 103", the admission certainly implies this and that is how the admission is hereby interpreted. Therefore, like *In re Lee*, it is concluded that the public interest is better served by withdrawing the restriction requirement and permitting both inventions to be prosecuted in the same application. At this point it is noted that the fact that there is an admission that the antibody is obvious in view of the peptide but not an admission that the peptide is obvious over the antibody would not change this decision because the Office policy that "no restriction requirements be made which might result in the issuance of two patents for the same invention" would still control.

In conclusion, the petition is granted and the examiner is directed to withdraw the requirement for restriction between Groups I/II and VI. Group VII remains restricted from Groups I/II/VI. The application is being returned to the examiner for appropriate action in a timely manner.

PETITION GRANTED.